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IN THE

Supreme Court of the United States

CHARLES R. RIEGEL AND DONNA S. RIEGEL, *Petitioners*

v.

MEDTRONIC, INC., *Respondent*

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF OF CONSUMERS UNION OF UNITED STATES, INC., AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

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BRIEF OF AMICUS CURIAE CONSUMERS UNION OF UNITED STATES, INC., IN SUPPORT OF PETITIONERS

STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

Consumers Union of United States, Inc., the publisher of *Consumer Reports*, is a non-profit membership organization chartered in 1936 to provide consumers with information, education, and counsel about goods, services, health, and personal finance. Consumers Union's publications have a combined paid circulation of approximately 8 million. These publications regularly carry articles reporting on Consumer Union's own product testing; health, product safety, and marketplace economics; and legislative, judicial, and regulatory actions that affect consumer welfare. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and services, and from noncommercial contributions, grants, and fees. Consumers Union's publications and services carry no outside advertising and receive no commercial support.

Consumers Union's mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. In line with that mission

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[1] The parties have lodged letters with the Court consenting generally to the filing of briefs *amicus curiae*, and accordingly, the parties have consented to the filing of this brief. See Sup. Ct. R. 37.3(a). No counsel for a party to this case authored this brief in whole or in part, and no person or entity other than *Amicus Curiae* Consumers Union, its members, or its counsel, made a monetary contribution to the preparation or submission of the brief. See Sup. Ct. R. 37.6.

and our assessment of priorities, Consumers Union has actively worked for a fair and just marketplace for consumers in critical areas implicated by this case, including health care and prescription drugs. From its beginnings, on through the present time, Consumers Union has filed actions in both state and federal courts to protect consumers, and has participated in a variety of proceedings before both state and federal regulatory agencies. Consumers Union played an active role in securing the passage of the Food, Drug, and Cosmetic Act of 1938 and the 1958 amendments to the Act. Consumers Union also filed an amicus brief in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), a decision of central importance to this case.

SUMMARY OF ARGUMENT

In 1996, Charles Riegel had an angioplasty performed on his right coronary artery. During the procedure, Mr. Riegel's surgeon used respondent Medtronic's Evergreen Balloon Catheter. The catheter burst inside Mr. Riegel's artery, causing Mr. Riegel severe and permanent injuries and disabilities. In addition, his wife, Donna Riegel, suffered a loss of companionship with her husband. The Riegels sued Medtronic, alleging common-law claims for, among other things, defective design and inadequate warning.

Nothing in the Food, Drug, and Cosmetic Act required Medtronic to manufacture and distribute a negligently and defectively designed catheter with negligently chosen labeling. The law aims higher than that, toward a state of affairs in which the manufacturers of medical devices and other products covered by the statute are under a continuing obligation to ensure the safety of their products.

Nevertheless, the court below held that the Riegels' state-law claims were preempted by the Medical Device

Amendments of 1976 to the Food, Drug, and Cosmetic Act. The court's sweeping ruling reflects a misunderstanding of the federal statute at issue, a misapplication of this Court's precedents, and a misreading of the specific provision on preemption in play in this case.

1. The Food, Drug, and Cosmetic Act aims to protect the health of American consumers by regulating foods, drugs, cosmetics, medical devices, and other products and technologies associated with health and health care. A careful reading of the statute reveals a regulatory system designed to set minimum standards for covered products and to press regulated entities to continually improve the safety of their goods. The Act, in its overall substance and structure, fits comfortably with state-created common law aimed at protecting the health and safety of American consumers and providing recompense to those injured through no fault of their own.

2. This Court's precedents on preemption dictate a close analysis of both the purportedly preemptive federal law and the purportedly preempted state rule. Indeed, the Court's recent cases in this area can only be understood by reference to the very specific legal settings from which they arose. These cases reflect the Court's traditional wariness about preempting state laws protecting health and safety. The care with which the Court in recent cases has examined the specific legal setting at issue reaffirms the Court's longstanding acknowledgment that federal preemption of state health and safety laws is strong medicine, not to be taken lightly.

3. This case falls within the line of decisions from this Court narrowly construing the scope of statutory preemption. The premarket approval of Medtronic's catheter by the Food and Drug Administration is not a "requirement"

absolving Medtronic of liability for negligence and other torts; preserving the Riegels' tort claims creates no tension with that approval; the standard for approving medical devices implies the existence of post-market remedies; and the history of tort litigation preceding the Medical Device Amendments of 1976 strongly reinforces the conclusion that these amendments do not preempt the claims at issue here.

ARGUMENT

I. The Food, Drug, And Cosmetic Act Sets Minimum Standards, Designed To Continually Improve The Safety Of Regulated Products, And Thus The Statute Fits Comfortably With State-Based Common Law Remedies.

In determining whether a federal statute preempts state law, this Court has repeatedly stressed the importance of close examination of the statute's text, history, and structure. See, *e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485-486 (1996). In undertaking this inquiry, the Court has found it necessary to look beyond specific provisions on preemption to the broader context of a regulatory scheme in order to responsibly decide the question of preemption. See, *e.g.*, *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869-874 (2000). Thus, before studying the preemption provision at issue here, a careful look at the broader context of the Federal Food, Drug, and Cosmetic Act is in order.

The Food, Drug, and Cosmetic Act is perhaps the premier consumer protection law in this country. Its basic structure dates back over 100 years, to the Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768. That early enactment created a regulatory framework which, despite many intervening amendments, still exists (albeit in modified form) today. The Medical Device Amendments of 1976 comprise but one piece of this venerable and complex statute. For this reason as well, the preemption provision of

these amendments cannot be well understood without an appreciation of the larger statutory framework of which it is a part.

Careful review of the statutory framework as it has evolved over time reveals several important features relevant to this case. First, in adding new requirements to the statute, Congress tended to keep in place the basic framework that had preceded them. The statute as originally developed in 1906 regulated foods and drugs. *United States v. Dotterweich*, 320 U.S. 277, 280 (1943). It protected American consumers against the twin evils of dangerousness and deception through prohibitions on "adulteration" and "misbranding." *62 Cases, More or Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 596 (1951). When Congress stiffened the requirements for drugs – in 1938, by providing for premarket review to assess safety, Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052, and in 1962, by requiring review to assess effectiveness, Drug Amendments of 1962, Pub. L. No. 87-781, § 102(a), 76 Stat. 780, 781 – it left the prohibitions against adulteration and misbranding in place. 21 U.S.C. §§ 331, 351. Congress did the same when it added premarket approval requirements for medical devices to the statute in 1976. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 515(a), 90 Stat. 539, 552-553; 21 U.S.C. §§ 331, 351. Thus, drugs and devices approved by the FDA are still subject to the law's prohibitions on adulteration and misbranding. The Food, Drug, and Cosmetic Act is, in short, a palimpsest, a tablet on which the newest layers of writing do not erase earlier ones. The Court should be exceptionally chary of an interpretation of the statute that would use a new regulatory layer (the Medical Device Amendments) to sweep away an old one (state-based remedies of the common law).

Second, while Congress often responded to emerging problems with broader or more stringent premarket review of consumer products, it also retained and strengthened statutory provisions creating a continuing obligation on the part of regulated entities to improve safety. Not only did Congress keep in place the prohibitions against adulteration and misbranding, even for products that had received premarket approval, but it also added provisions designed to ensure post-market vigilance in matters of safety. See, *e.g.*, 21 U.S.C. § 360h(e) (authorizing FDA to recall devices); 21 U.S.C. § 360h(e)(1)(B) (requiring notification to doctors and hospitals of dangerous devices); 21 U.S.C. § 360*l* (establishing requirements for post-market surveillance). These provisions demonstrate Congress's understanding that the premarket approval process sets a minimum standard for regulated products, one that sometimes proves inadequate in light of subsequent consumer and market experience. Preservation of state-based tort claims is a complement, not an affront, to this statutory scheme.

Third, the Food, Drug, and Cosmetic Act regulated medical devices long before the Medical Device Amendments of 1976. The 1938 enactment added the category of "device" to the products regulated under the Act. See *United States v. Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 796-797 (1969). Under this statute, the prohibitions against adulteration and misbranding were applied to medical devices. *Id.* at 797; Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No 75-71, § 301(a), 52 Stat. 1040, 1042. Thus medical devices became subject to the same protections against dangerousness and deception that had long been applied to foods and drugs.

The 1938 statute did not, however, apply the process of premarket safety review to devices. The absence of a requirement of premarket safety approval, combined with

the recognition of the strong public health purposes of the Act, persuaded this Court to extend the premarket approval requirements applicable to drugs to items that, in truth, looked a lot more like devices than drugs. In *Bacto-Unidisk*, the Court held that devices used in the laboratory to test the sensitivity of certain microorganisms to certain antibiotics (aptly called "antibiotic sensitivity discs") were "drugs" and thus were subject to the Act's requirements for premarket safety review. 394 U.S. at 793-798. Although the discs never touched a patient's body, the Court thought that the Act's "overriding purpose to protect the public health" counseled in favor of broad construction of the Act. *Id.* at 798. The practical effect of the Court's ruling was to subject the antibiotic sensitivity discs to the same premarket approval process applied to drugs. The decision in *Bacto-Unidisk* is of a piece with other decisions from this Court recognizing "the high purpose of the Act" in protecting consumers. *Kordel v. United States*, 335 U.S. 345, 349 (1948).

Fourth, state-based tort claims have peacefully co-existed with the federal regulatory framework for many decades. Foods and drugs regulated by the Food, Drug, and Cosmetic Act remained subject to state-based common law claims not only in the period between 1906 and 1938, when the federal requirements applicable to them were the prohibitions on adulteration and misbranding. See, *e.g.*, *Mazetti v. Armour & Co.*, 75 Wash. 622 (Wash. 1913); *Moehlenbrock v. Parke, Davis & Co.*, 141 Minn. 154 (Minn. 1918); *Hruska v. Parke, Davis & Co.*, 6 F.2d 536 (8th Cir. 1925); *Machlitt v. Myers*, 23 Ohio App. 160 (Ohio App. 1926); *Coca Cola Bottling Works v. Selvidge*, 4 Tenn. App. 558 (Tenn. App. 1927); *Ritchie v. Sheffield Farms Co.*, 222 N.Y.S. 724 (N.Y. Mun. Ct. 1927); *Abbott Labs. v. Lapp*, 78 F.2d 170 (7th Cir. 1935). Drugs also remained subject to tort claims even after 1938, when Congress added the provisions creating a premarket review process for drugs. See, *e.g.*, *Wennerholm v. Stanford Univ. Sch.*

of Med., 128 P.2d 522 (Cal. 1942); *Wechsler v. Hoffman-La Roche, Inc.*, 99 N.Y.S.2d 588 (N.Y. Sup. 1950); *Berry v. Am. Cyanamid Co.*, 341 F.2d 14 (6th Cir. 1965); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966); *Love v. Wolf*, 58 Cal. Rptr. 42 (Cal. Ct. App. 1967); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967); *Toole v. Richardson-Merrell Inc.*, 60 Cal.Rptr. 398 (Cal. Ct. App. 1967); *Fritz v. Parke Davis & Co.*, 277 Minn. 210 (Minn. 1967); *Williams v. Vick Chemical Co.*, 279 F. Supp. 833 (S.D. Iowa 1967); *Bine v. Sterling Drug, Inc.*, 422 S.W.2d 623 (Mo. 1968); *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1968); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969); *Tinnerholm v. Parke, Davis & Co.*, 411 F.2d 48 (2d Cir. 1969); *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969); *Grinnell v. Charles Pfizer & Co.*, 79 Cal.Rptr. 369 (Cal. Ct. App. 1969); *Kershaw v. Sterling Drug, Inc.*, 415 F.2d 1009 (5th Cir. 1969); *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970); *Hornung v. Richardson-Merrill, Inc.*, 317 F. Supp. 183 (D. Mont. 1970); *Croft v. York*, 244 So.2d 161 (Fla. App. 1971); *Singer v. Sterling Drug, Inc.*, 461 F.2d 288 (7th Cir. 1972); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal. 1973); *Redfield v. Mead, Johnson & Co.*, 266 Or. 273 (Or. 1973); *Hoffman v. Sterling Drug, Inc.*, 374 F. Supp. 850 (M.D. Pa. 1974); *Reyes v. Wyeth Labs.*, 498 F.2d 1264 (5th Cir. 1974); *Crocker v. Winthrop Labs., Div. of Sterling Drug, Inc.*, 514 S.W.2d 429 (Tx. 1974); *McEwen v. Ortho Pharm. Corp.*, 270 Or. 375 (Or. 1974); *Whitley v. Cubberly*, 210 S.E.2d 289, (N.C. Ct. App. 1974); *Oresman v. G. D. Searle & Co.*, 388 F. Supp. 1175 (D. R.I. 1975); *Henry v. Richardson-Merrell, Inc.*, 508 F.2d 28 (3d Cir. 1975); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359 (4th Cir. 1975). Of course, this is only a partial list of the actual cases; in particular, the list stops at 1975. This end date has a substantive objective: the listed cases were all on the books when Congress enacted the Medical Device Amendments of 1976. If Congress wanted to avoid the history of tort litigation that had accompanied drugs even after the creation of the premarket review process in 1938, one would have

expected a different statement than the one provided in the preemption provision Congress chose.

When medical devices were added to the statutory mix in 1938, they, too, remained subject to state-based tort claims. In fact, in the ensuing decades, courts entertained many tort suits relating to medical devices. See, *e.g.*, *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960) (upholding jury ruling in favor of plaintiff in action against manufacturer of surgical nail); *Vergott v. Deseret Pharm. Co.*, 463 F.2d 12 (5th Cir. 1972) (upholding tort-based jury verdict against manufacturer of needle used for catheter, which broke off in plaintiff's vein); *Dreiling v. Gen. Elec. Co.*, 511 F.2d 768 (5th Cir. 1975) (upholding jury verdict for defendant in case involving allegedly defective pacemaker); *Cinocca v. Baxter Lab.*, 400 F. Supp. 527 (E.D. Okla. 1975) (denying summary judgment to corporate successor of firm that manufactured allegedly defective heart valve); *E.R. Squibb & Sons., Inc. v. Jordan*, 254 So.2d 17 (Fla. App. 1971) (remanding for new trial on question whether beef bone processed and marketed by defendant and used in spinal operation was defective); *Friedman v. Medtronic, Inc.*, 345 N.Y.S.2d 637 (NY App. Div. 1973) (jury verdict for plaintiff, alleging breach of implied warranty with respect to pacemaker, overturned on appeal).

Indeed, the tort system itself played no small part in galvanizing support for the very 1976 amendments alleged to preempt relief in this case. In the early 1970s, reports emerged about serious safety problems associated with medical devices. Most famously, thousands of women who used the Dalkon Shield were injured by it, and some died. S. Rep. 94-33, at 6 (1975), 94 Cong. 2d Sess., *as reprinted in* 1976 U.S.C.C.A.N. 1070. Lawsuits sprang up all over the country, to such an extent that eventually a multidistrict panel on litigation was convened to deal with the numerous claims. *In*

re A. H. Robbins Co., Inc. "Dalkon Shield" IUD Prod. Liab. Litig., 406 F. Supp. 540 (J.P.M.L. 1975). In 1976, in the midst of this episode, Congress passed the Medical Device Amendments - without so much as a whisper suggesting that the Dalkon Shield lawsuits (or the many other lawsuits that had been brought relating to medical devices) might be undone by the statute it had passed. *Lohr*, 518 U.S. at 490-491 & n. 13.

Fifth, this Court's decisions construing the Act have respected, even celebrated, the protective purposes of the statute. The Act, Justice Frankfurter wrote in 1943, touches "phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words." *Dotterweich*, 320 U.S. at 280. At the same time, the Court has underscored the Act's goal of encouraging continuous efforts to improve safety by holding corporate officials responsible for dangers within their reach: "[I]n providing sanctions which reach and touch the individuals who execute the corporate mission . . . the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur." *United States v. Park*, 421 U.S. 658, 672 (1975). Acknowledging that "[h]ardship there doubtless may be" under such a system, the Court has recognized that Congress chose to place the hardship "upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are totally helpless." *Dotterweich*, 320 U.S. at 284-285. The application of tort law to matters embraced by the Act is fully consistent with the Act's large purpose of promoting responsible

commerce. In truth, it would be a deep irony if this same statute were held to displace one of the few avenues consumers have to engage in self-help against irresponsible commerce - state-based common law.

In sum, a finding that tort law remains as a complement to the regulatory framework of the Food, Drug, and Cosmetic Act is perfectly consistent with - and indeed, congenial to - the history and structure of the statute as a whole.

II. This Court's Recent Rulings On Preemption Must Be Understood With Reference To The Specific Regulatory Settings In Which They Arose.

This Court has long recognized that federal preemption of state laws related to health and safety is a delicate matter. Indeed, the Court has frequently invoked "the assumption that the historic police powers of the States were not to be superseded by [federal statute] unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

This solicitousness toward state protections of health and safety is evident in the modern regulatory era. In *Silkwood v. Kerr-McGee Corp.*, the Court held that a claim for punitive damages relating to the operation of a facility that made plutonium fuel pins was not preempted by the Atomic Energy Act. 464 U.S. 238, 258 (1984). Based on a painstaking analysis of the text and history of the relevant federal statutes, the Court found that Congress had all along assumed that state tort law would remain viable even in the midst of the massive federal regulatory regime applicable to nuclear facilities. *Id.* at 248-258.

Likewise, in *Cipollone v. Liggett Group, Inc.*, the Court meticulously scrutinized the textual differences between the Federal Cigarette Labeling and Advertising Act of 1965 and the Public Health Cigarette Smoking Act of 1969 in coming to its conclusion that the latter statute, but not the former, preempted some common law claims. 505 U.S. 504, 518-524 (1992). The Court further scrutinized the 1969 statute in order to figure out precisely which common law claims had been preempted. *Id.* at 524-531. Based on a close reading of the statutory text, the Court found that failure-to-warn claims were preempted, but claims based on breach of express warranty and fraudulent misrepresentation were not. *Ibid.*

The Court's decision in *Cipollone* has been regarded by some observers as a watershed moment in preemption history, insofar as it appears to be the first case in which this Court held that a federal statute preempted a state products liability claim even where the federal law provided no individual remedy of its own. See David Owen, *Federal Preemption of Products Liability Claims*, 55 S.C. L. REV. 411, 423 (2003). In addition, the Court's reading of the 1969 statute's language of "requirements" to include state common law claims inspired fear that the decision presaged a large-scale turn away from the Court's traditional reluctance to set aside state laws protecting health and safety. And indeed, this concern appeared well founded when *Cipollone* spurred a whole new wave of preemption litigation. See David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 106 (2005). Nevertheless, a close reading of the decision reveals the Court doing the work it has always done in preemption cases: assiduously comparing the allegedly preemptive federal statute with the specific state-law claims being pressed.

This narrower understanding of the implications of *Cipollone* has been validated by subsequent decisions of this Court. The Court's next major pronouncement on the relationship between an allegedly preemptive federal law and a state tort claim came in the context of the same statute at issue here. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, the Court held that the Medical Device Amendments did not - despite their use of the term "requirements," the interpretation of which had led to such a ruckus following *Cipollone* - preempt state common-law claims based on negligent design, manufacturing, and labeling. 518 U.S. 470, 501-503 (1996).

In *Lohr*, the plurality came within a whisker of holding that the Medical Device Amendments simply did not preempt tort claims at all, but refrained from deciding the question conclusively because it was not necessary to dispose of the case. 518 U.S. at 502-503. In preserving the tort claims at issue there, the Court found that "generic concerns about device regulation generally" were not the sorts of federal "requirements" that would lead to preemption under the statute, *id.* at 501, and that general state common-law claims likewise were "not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Ibid.* The Court in *Lohr* was, above all else, concerned with actual inconsistencies between federal and state requirements, not with an abstract potential for tension.

The same preference for the specific statutory language and intent over abstract possibilities carried the day in the Court's unanimous decision in *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002). In construing the express preemption provision in the Federal Boat Safety Act, the Court found it "perfectly rational for Congress not to pre-empt common-law claims, which - unlike most administrative and

legislative regulations - necessarily perform an important remedial role in compensating accident victims." *Id.* at 64. The Court also found that the Coast Guard's general declination to set propeller guard standards for boats was perfectly consistent "with a tort verdict premised on a jury's finding that some type of propeller guard should have been installed on this particular kind of boat equipped with respondent's particular type of motor." *Id.* at 67.

Even more telling is the Court's recent decision in *Bates v. Dow Agroscience LLC*, 544 U.S. 431 (2005). While holding that the word "requirements" in the preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) referred to at least some state-based common law claims, the Court also held that the fact that the provision preempted "judge-made rules, as well as statutes and regulations, says nothing about the *scope* of that preemption." *Id.* at 443-444. The Court narrowed the class of common-law claims that might be preempted by FIFRA by focusing on the statutory phrases qualifying the word "requirements." *Id.* at 444. In addition, the Court narrowed even the scope of what might be regarded as "requirements" by excluding tort principles that merely induced particular action on the part of pesticide manufacturers:

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue; it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action (a question, in any event, that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants).

Id. at 445 (citation omitted).

Even where the Court found that the common-law claims at issue in *Bates* fell within the statutory definition of "requirements," the Court found that they were not preempted if they "were equivalent to, and fully consistent with," the federal provisions. *Id.* at 447. Here, the Court called upon statutory language strikingly similar to that contained in the Medical Device Amendments, and found that it preserved state-law claims so long as they were parallel to federal requirements. *Id.* at 447-448 (relying on *Lohr*, 518 U.S. at 495).

Significantly, the Court in *Bates* found support for its ruling in "the long history of tort litigation against manufacturers of poisonous substances." *Id.* at 449. The Court thought that this history not only "emphasizes the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items," *id.* at 450, but that it also made it "unlikely" that Congress used a "relatively obscure provision" to erase this traditional liability. *Id.* at 450. The Court also thought that tort liability could "aid, rather than hinder," the operation of the federal statute, particularly since the statute contemplated that the pesticide labels governed by the statute "will evolve over time." *Id.* at 451.

The cases relevant here are, in short, both complex and pragmatic. The cases are complex as a result of the Court's salutary insistence on digging deep into the details of the putatively preemptive federal scheme and comparing them to the details of the putatively preempted state laws. The cases are pragmatic insofar as they are alert to the way in which Congress is likely to express an intent to displace state law. The Court's decision in *Bates* is especially instructive on the latter point, as the Court thought it improbable that

Congress would subtly undo a long history of state-based tort litigation.

The appeals court's decision in this case shows none of the subtlety and pragmatism that characterize this Court's preemption cases. In place of complex and concrete analysis of exactly how the federal law on medical devices relates to the tort claims at issue here, the court offered generalized anxiety about the abstract potential for conflict between the federal and state schemes. *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 121-123 (2d Cir. 2006). And in place of a realistic appraisal of how Congress is likely to express an intent to displace longstanding tort principles, the court vaguely opined that "it is much less clear" that these principles survived creation of the premarket review process for the most dangerous medical devices. *Id.* at 123.

III. The Medical Device Amendments Do Not Preempt The Petitioners' Tort Claims.

Petitioners' brief explains in detail why petitioners' tort claims survive the narrow preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a). We adopt these arguments. In this closing section, we highlight several points that might not stand out in petitioners' comprehensive discussion of the relevant issues.

First, this case is very different from *Cipollone*. There, the federal statute dictated the contents of the labels on cigarette packages. Cigarette makers were not allowed to deviate from those mandates. Here, in contrast, the FDA simply approved an application developed and submitted by Medtronic. Approval without specific, prescriptive conditions is not a "requirement"; it is more a dispensation than a dictate. Nothing in the FDA's approval required Medtronic to manufacture or distribute a defective device,

inadequately labeled. Even if the FDA had listed some conditions of approval, generic common-law duties and remedies such as the duty of care and the duty to warn would not conflict with those device-specific conditions.

Second, the preceding point highlights the lack of conflict here between the federal and state frameworks. Medtronic was not required, to borrow Justice Breyer's formulation from his partial concurrence in *Lohr*, to use the catheter-equivalent of a two-inch wire, 518 U.S. at 503-508, and petitioners' prayer for tort relief asks for nothing inconsistent with the FDA's approval of Medtronic's catheter. If petitioners prevailed on their tort claims, Medtronic would not be caught in a bind between federal and state compliance. This case thus does not present the potential for conflict that concerned Justice Breyer in *Lohr*. Indeed, it bears noting that Medtronic no longer even makes the Evergreen Balloon Catheter. In this case, even a potential for tension between federal law and state remedies is nonexistent.

Third, the criterion for premarket approval of medical devices itself points to the contingent and preliminary nature of the FDA's decision, reinforcing our earlier point that the premarket approval process is complemented by post-market controls, including tort law. The standard for approval of medical devices is "reasonable assurance" of safety. 21 U.S.C. § 360e(d)(2)(A), (B). The hopeful but tentative nature of this standard appears to assume the availability of the kind of post-market discipline embodied in tort-based remedies. See *also* 21 U.S.C. 306h(d) (offset provision regarding economic damages recovered under federal or state law, embodying background assumption of tort liability).

Fourth, the abundant tort actions relating to medical devices entertained by the courts prior to 1976 parallel the long history of tort litigation relating to poisonous substances, emphasized by this Court in *Bates*. 544 U.S. at 449-450. Here, as there, it is improbable that Congress would undo these longstanding remedies with a provision that does not even mention the common law. Equally telling is the rich history of litigation relating to drugs, discussed in Part I above, following the creation of the premarket review process for drugs. If Congress had wanted, in creating the premarket review process for medical devices, to avoid the tort litigation that had for decades complemented the premarket review process for drugs, it is reasonable to expect that it would have said so in plain terms.

Every day in this country, consumers must trust strangers to provide them with uncontaminated food, good medicine, honest financial services, safe cars, and the whole host of other products and services associated with modern life. Congress has passed a wide variety of laws aimed at promoting a fair and safe marketplace. Longstanding principles of tort, such as the duty of care and the duty to warn, are fixed on the same goal, albeit with the added aim of compensating victims of wrongful conduct. It has been, and should continue to be, the most unusual case when this Court upends the friendly collaboration between federal laws and state tort remedies. This is not that case.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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